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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,615	11/13/2000	Kenneth F. Buechler	230/006	4653

30542 7590 07/28/2006

FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/28/2006

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/712,615
Filing Date: November 13, 2000
Appellant(s): BUECHLER ET AL.

Barry Wilson
Reg. No. 39,431
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 17 November 2005 appealing from the Final Office action mailed 5 May 2005.

(1) Real Party in Interest

A statement identifying Biosite Incorporated (formerly Biosite Diagnostics, Inc.) by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

This appeal involves claims 27, 28, and 93-128.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

A.	5,458,852	BUECHLER	October 17, 1995
B.	5,132,097	VAN DEUSEN et al.	July 21, 1992
C.	5,242,837	SLOVACEK et al.	September 7, 1993
D.	4,444,879	FOSTER et al.	April 24, 1984

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

I. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 27, 28, and 93-128 the use of "timing zone" is vague and indefinite because it is not clear as to what the term is to encompass. Is the zone merely to evaluate the reactions end wherein a signal is evaluated with respect to reagent flow? As recited the term "timing zone" is a relative term, which renders the claim indefinite. The term "timing zone" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

B. In claims 27 and 113 the interaction of the "timing zone" is not clear. The apparatus requires two separate zones. Specifically, an assay zone and a timing zone; both are located on a diagnostic lane wherein a detectable label flows through the diagnostic lane. However the relationship between the two individual zones is not recited. It is not clear that the timing zone is located down stream from the assay zone so that it can measure the time of assay completion. Further the label does not clearly bind to either of the zones to produce a detectable product. What binds the detectable label (analyte, IAC,etc), is it already detectable before addition, how does it related to the zones of the diagnostic lane. As recited the label merely flows through the diagnostic lane and does not produce a detectable signal in either the assay zone or the timing zone. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

II. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All the claims are directed to device/apparatus with at least one timing zone separated from the assay zone. The disclosure does not show support for this limitation. For example page 15 lines 19-28 of the specification cited by Applicants does not provide support. Therefore the limitation is considered new matter. Applicant is invited to show support for the "timing zone separated from the assay zone" in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

III. Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097).

Buechler discloses assay devices meeting the requirements of the instant invention. This is supported by the specification on page 59, lines 21-28. Particularly Buechler's device comprises a reaction chamber (column 6) and a diagnostic lane (column 10 –diagnostic element). See figures 1-5, item #4 (reaction chamber, column 6 and 7), item #17 (optional reagent chambers, column 8 and 9, and item # 6 (diagnostic element, column 10).

The device includes a time gate for measuring the reaction in a given period of time. Pleas see column 7 lines 41-45. The device is useful in measuring an absolute signal or a rate of change of the signal. Particularly determining the presence or amount of each target ligand in the sample either visually or instrumentally. Column 17, lines 44-46. The rate of change is monitored via the flow rate of reagents through the porous member. Column 18, lines 2-9. Further the label (signal development element) does not appreciably bind to any reagent in said assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process. Column 3, lines 17-25.

The apparatus of Buechler further includes an optical system for detecting and processing optical signals generated from the label in the diagnostic lane. Column 20 lines 22-31.

Buechler differs from the instant invention in not specifically disclosing the detailed structure of the optical system including an optical component and a signal processor specifically configured to read electronic signals.

However, such an optical system is considered conventional in the assay art, see Van Deusen et al. Van Deusen et al. teach devices having both an optical signal detector and signal processor. Van Deusen et al. disclose an apparatus for analyzing specific binding complexes.

A test strip having a reactive surface coated with a specific binding member is employed and laser analysis allows for detection via a detector assembly (processor). See abstract, Column 2, 55-68 through columns 3, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device as taught by Buechler to perform immunoassay detection procedures, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35). Further such an optical detector and signal processor are always required in an optical system in order to detect and process the signals generated from the labels.

One having ordinary skill in the art would have been motivated to do this to greatly reduce the time required for analysis and improve reagent flow. Van Deusen Column 3, lines 20 –21.

IV. Claims 95 and 117 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

V. Claims 28, 101, 102, 104, 107-108 and 127-128 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 above, and Foster et al. (U.S.Patent#4,444,879).

The teachings of Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. are set forth above. However, these references fail to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

VI. Claim 103 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. and in further view of in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 28, 101, 102, 104, 107-108 and 127-128 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and in further view of Zuk et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

Allowable Subject Matter

VII. Claims 97, 98, 105, 106, 119, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(10) Response to Argument

Claim Rejections - 35 USC § 112

VIII. Applicant contends that definiteness is not analyzed in a vacuum but must be considered in light of the specification and the knowledge available to the skilled artisan. In support of this position Applicant cites pages 13-14, 40-42, 70-71, and 73-75 of the specification.

This argument was carefully considered but not found persuasive because the specification does not define the term "timing zone" as a separate zone from the assay zone wherein a measurable signal is generated in connection with but independent of the signal obtained for the analyte of interest (page 8 of the response faxed 8/18/04).

Specifically, the specification teaches multiple discrete zones on page 13 line 12, but does not recite that the signal is measured in a "timing zone". Although a timing function is taught beginning on page 40 no "timing zones" are recited. The section of the specification directed to the *Use of the Timing Signal to Detect Assay Completion of Immunoassay devices* starting on page 73 describes a "timing zone" contrary to Applicants arguments. This section of the disclosure appears to teach a "timing signal zone" or "timing zone" along the entire diagnostic lane wherein a signal is measured every ten seconds by window advancement over the discrete zones of the device (See page 73 lines 13-25).

There is no requirement for an assay zone and a separate "timing zone" or a "timing zone" monitoring a measurable signal that is independent of the analyte.

With respect to the skilled artisan, it is noted that "timing zone" is not an art recognized term and appears to encompass different meanings in the prior art as evident by the STN search conducted on 4/29/05 (See attachment A). If there are multiple definitions for a term, it must be clear from the application as filed that applicant intended a particular definition, in order to avoid an issue of new matter and/or lack of written description.

Therefore, it is maintained that the term "timing zone" is unclear, relative, and not supported by the instant specification. When the scope of the claims can't be determined when considered in light of the specification, a rejection under 35 USC 112, second paragraph, is proper. In re Wiggins, 488 F2d 538, 179 USPQ 421 (CCPA 1973). The rejections under 112 paragraph are maintained.

Applicant also contends that no particular relationship between the assay zone(s) and the timing zone is required and no label is required for evaluation in the timing zone. The timing zone may be placed in front of the assay zone and the timing zone measurements may be conducted empirically. This argument was carefully considered but not found persuasive because the claims are directed to an apparatus that measures "progress and time of completion of an assay for an analyte". How will the time of completion be determined in the timing zone when it is placed in front of the assay zone? Further if no label exits in the zone it is not clear how one will determine that the assay has progressed to completion. Accordingly the rejections are maintained.

Claim Rejections - 35 USC 103 rejections

IX. In response to applicant's argument that there is no suggestion to combine the references of Buechler (US Patent #5,458,852) in view of Van Deusen et al. (US Patent #5,132,097), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device as taught by Buechler to perform immunoassay detection procedures, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35) and an optical detector and signal processor are always required in an optical system in order to detect and process the signals. The signal processor would greatly reduce the time required for analysis. Van Deusen Column 3, lines 20 –21.

Applicant contends that the "time gate" of the '852 patent is not involved in measuring any reaction. This argument was carefully considered but not found persuasive because the claims merely require a timing zone and an assay zone in fluid communication. In the '852 patent the "time gate" (timing zone) is in fluid communication with a diagnostic element (assay zone) and utilized in immunoassays. See column 7 line 40 – column 8 line 50.

Applicant further contends that the reference of Buechler et al. does not detect any signal whatsoever in the timing zone but measures a resistance that holds the reaction mixture in the reaction chamber for a given period of time (time gate). This argument was carefully considered but not found persuasive because the instant disclosure teaches the same inventive concept with respect to the claimed apparatus.

Specifically the specification teaches that the "assay devices....comprise a time gate control and a flow control". The controls include IAC, which are employed to measure completion by signal generation. See page 60 lines 23-26 for example.

However the cited claims do not include IAC's in the timing zone nor do they clearly set forth that a detectable signal is generated to measure assay completion, therefore there is no requirement for the Buechler et al. reference to teach IAC signal detection.

Applicant argues that Buechler et al. in view of Van Deusen et al. do not teach a timing zone configured to bind a detectable label, which does not bind appreciably to the assay zone. This argument was carefully considered but not found persuasive because the instant disclosure does not have support for the aforementioned limitations.

Applicant argues that the "time gate" is not configured to provide a signal, however the "time gate" houses the reaction mixture that includes signal-producing reagents. See column 14 line 26 and lines 50-52.

With respect to the language "configured to detect", Applicant argues this represents structural elements that must be considered. However, the structural elements have not been included in the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., structural elements reading on "configured to") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant contends that the '852 patent does not measure a signal in the "time gate", however signal producing reagents are added to the time gate. See column 14 line 26 and lines 50-52. There is no requirement that the prior art must suggest that the claimed product (apparatus) will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, 16 USPQ.2d 1897, 1904, (Fed. Cir. 1990).

The test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. See *In re Bent*, 52 CCPA 850, 144 USPQ 28 (1964).

In response to the argument that the primary references fail to teach a processor configured "to determine process and time of completion of an assay from a timing zone", it is noted that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicant contends that the references do not include a "timing zone" wherein an independent assay control signal (IACS) is detected for use in determining if the assay for the analyte of interest has run to completion. This argument was carefully considered but not found persuasive because the claims do not recite that the "timing zone" includes IACS. As written the timing zone merely has to be apart of the diagnostic lane and separate from the assay zone. No reagents are included in the timing zone to allow for signal generation for detection.

With respect to all other claims applicant argues that primary '852 and secondary '097 patents do not teach the instant invention and therefore cannot be combined to teach the other dependent claims. The arguments have been addressed above for primary '852 and secondary '097 patents.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Lisa V. Daniels-Cook

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferees:

Long Le, Spe 1641

Larry Helms, Spe 1643

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER